

Message

From: Jakob, Avivah [Jakob.Avivah@epa.gov]
Sent: 5/16/2017 2:24:10 AM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: Beck, Nancy [Beck.Nancy@epa.gov]
Subject: Re: GM mosquitos

Thanks!

(CC'ing Nancy)

Sent from my iPhone

On May 15, 2017, at 6:08 PM, Keigwin, Richard <Keigwin.Richard@epa.gov> wrote:

There isn't a legal deadline by which FDA has to finalize the guidance. One thought is that they might keep the guidance as draft for this use season so as not to jeopardize potential use for this year's mosquito season.

Rick Keigwin
Acting Director, Office of Pesticide Programs
U.S. Environmental Protection Agency

Sent from my iPhone

On May 15, 2017, at 5:51 PM, Jakob, Avivah <Jakob.Avivah@epa.gov> wrote:

One more. Is there a timeframe by which FDA has to finalize the guidance? And/or do we have a sense as to when FDA expects to finalize/publish?

(Background doc says its awaiting approval by senior FDA officials and has not yet been published)

Thanks!!!!
AJ

From: Keigwin, Richard
Sent: Monday, May 15, 2017 2:03 PM
To: Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: RE: GM mosquitos

- <!--[if !supportLists]--><!--[endif]-->FIFRA Section 18 Emergency Exemption – EPA can consider an application from a state or federal agency in coordination with Oxitec for an emergency exemption of the product under FIFRA Section 18 which would allow use of the product. EPA OGC currently believes a Section 18 exemption cannot be issued prior to publication of FDA final guidance.
- <!--[if !supportLists]--><!--[endif]-->FIFRA Experimental Use Permit (EUP) – EPA can accept an Oxitec application for environmental testing of the product under the

FIFRA Section 5 EUP provisions and issue an EUP even if FDA's final guidance has not published. Under the Pesticide Registration Improvement Act (PRIA), EPA has up to 7 months to complete such a review, but we would expedite our review if possible.

From: Jakob, Avivah
Sent: Monday, May 15, 2017 1:47 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Subject: RE: GM mosquitos

In the meantime, we can accept application for either an EUP or Section 18, right?

Thanks.

From: Keigwin, Richard
Sent: Monday, May 15, 2017 1:31 PM
To: Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: RE: GM mosquitos

Yes. FDA has previously asserted jurisdiction over the product. As a result, we have to wait for FDA to finalize their guidance (which would allow them to back down from their assertion of jurisdiction) before we can complete the transfer.

From: Jakob, Avivah
Sent: Monday, May 15, 2017 1:29 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Subject: RE: GM mosquitos

Rick- Nancy wants to know if there's a reason we have to wait for FDA's finalized guidance before formally transferring jurisdiction?

From: Keigwin, Richard
Sent: Friday, May 12, 2017 8:39 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: Re: GM mosquitos

This link will bring you to two documents: the updated coordinated framework and the new national strategy.

<https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/modernizing-regulatory-system-biotechnology-products>

Rick Keigwin
Acting Director, Office of Pesticide Programs
U.S. Environmental Protection Agency

Sent from my iPhone

On May 12, 2017, at 8:05 AM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Thanks! If you can send me a link to the coordinated framework, hopefully these 2 documents will do the trick.

Nancy B. Beck, Ph.D., DABT
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From: Keigwin, Richard
Sent: Friday, May 12, 2017 6:28 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>
Cc: Wise, Louise <Wise.Louise@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: GM mosquitos

Here's a background paper that we prepared a few weeks ago in response to some questions from Senator Inhofe's staff. It's what I have readily available; if you would like to get a deeper dive, we can get you something the early part of next week.

From: Beck, Nancy
Sent: Thursday, May 11, 2017 7:43 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>
Cc: Wise, Louise <Wise.Louise@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: GM mosquitos

Ex. 5 - Deliberative Process

Thanks!
Nancy

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